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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/964,120 | 09/25/2001 | Marvin L. Schilling | BWS-00-07 | 9970 |

7590 09/24/2002
BERND W. SANDT
900 Deerfield Court
Midland, MI 48640

EXAMINER

GOLLAMUDI, SHARMILA S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 09/24/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,120

Applicant(s)

SCHILLING ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment A filed on June 5, 2002 is acknowledged. Claims 1-17 are included in the prosecution of this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "recovering a product in its original structure." It is not understood how a substance that has been subjected to dehydration and the steps recited in claim 1, retains its original structure. Is the limitation intended to convey that the active component retains its original structure? Further clarification is requested.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

The arguments regarding Ericcson have been fully considered but they are not persuasive. Applicant argues that Ericcson does not teach extracting the material in its original structure and the reference includes a fermenting process. Further, it is argued that Ericcson uses alcohol and admits it denatures the product.

As set forth above, that the examiner does not understand how the process of dehydration of an organic substance as seen in instant application, can retain its original

structure after heating. Further, the examiner points out that the step of comminuting the organic substance itself as seen in instant specification does not allow the organic substance to retain its original structure. The new limitation in claim 1 will be read in the light that the applicant intended to convey that the active product retains its original structure. The examiner points out that on column 4, lines 40-50 Ericcson teaches the use of low temperatures to avoid denaturing the active agent; therefore the active agent retains its original structure since the denaturing of a protein involves the loss of the native three dimensional configuration. Further, the examiner points out that it is within the skill of a practitioner in the art to exclude the fermentation step taught by Ericcson depending on the desired end product. Lastly, Ericcson clearly points out in lines 49-51 of column 4 that the use of excessive concentration should be avoided if the active form is desired and since the process of extraction is known in the art, one of ordinary skill would know what the level of alcohol would denature the active agent. Ericcson also teaches the solvent contains water and ethanol and/or phosphate buffered solution. The animal extract solvent does not contain alcohol, rather a phosphate saline solution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericcson et al (5733241) in view of Moore (5645851) or Maret (3878197).

Ericsson discloses the method of preparing bioactive extracts. The reference also teaches the method of extracting active agents from plant material or animal material. The method involves macerating the plant material and distilling with ethanol (col. 10-25). The reference teaches the plant material to yield essential oils. The reference teaches reducing moisture content to less than 14% and plant material can be dried at temperatures of 100-140 degrees F (col.2, lines 46-48). The reference teaches using different solvents for yielding different active substances. For instance, proteins and carbohydrates require water, ethanol, sodium, phosphates, and potassium. Plant materials require ethanol and water to provide a good extraction. (Note col. 4, lines 12-20). The method for animal tissue (organs or glands) involves macerating the tissue and adding a solvent containing NaCl, KCl, etc. For extracting proteins and alkaloids, the temperature of distillation should be low in order not to denature the active material. (Note col.4, lines 20-51).

Ericsson et al do not teach soaking the organic material in antimicrobial solution.

Moore teaches the obtaining Type II collagen from chicken cartilage (abstract). The chicken is soaked in a solution containing sodium chlorite to remove surface contamination. The cartilage is removed from the chicken flesh and soaked in hydrogen peroxide to sterilize the cartilage without denaturing the protein. (Note example 1). The product of example 1 can be dried at an average temperature of 110 Fahrenheit to remove the water content (example 12). The end product is used for treating individual with arthritis.

Maret teaches a process of extracting aloe vera. The process includes rinsing the leaves with chlorine solution to sterilize the leaves. The gel is then extracted and digested with a solution containing KCl to provide aloe vera juice (column 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to rinse or soak the organic material with an antimicrobial agent in order to eliminate surface contaminants as taught by Moore and Maret.

Claims 1-2, 4-6, 8, 12, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 359088065 in view of Ueno et al (4789497).

JP teaches the immersing bone or marrow in sodium hypochlorite, adding aqueous solution of lecithin, mixing, grinding, and heating the mixture. The active substance is then dehydrated. This method produces a material rich in nutrients. (Note abstract).

JP does not teach the use of NaCl or KCl in the solution.

Ueno et al teach the process of dehydration of fish meat.

Ueno teaches dehydration removes extra water and the well-known method of dehydration using sodium chloride at the time of washing. Ueno et al teaches the object of washing to remove factors that cause denaturation of proteins (col. 1, line 16 and lines 44-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use NaCl or KCl in JP's method of dehydration since Ueno teaches the state of the art in regards to dehydration. One would be motivated to add the salts to facilitate dehydration and although JP does not explicitly teach salts in the

solution, it is common practice in the art of dehydration. Further, the underlying mechanism of dehydration using salts whether it is for bone, cartilage, or meat, is the same.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for

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Art Unit: 1616

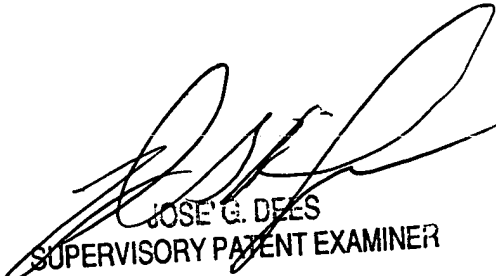
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the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG


September 10, 2002


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616